A Virtual TRIAL CAMPUS

CLINICAL-TRIAL AND MEDICAL-RESEARCH PROCESSES ARE INEFFICIENT. Two of the most inefficient areas are communications and training. ONCE THESE PROCESSES ARE STREAMLINED AND STANDARDIZED THE REST CAN FALL INTO PLACE .

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, AL OVIEDO PACINO II, PRESIDENT OF HILLICON TRAININGCAMPUSES, DISCUSSES THE NEED FOR EFFICIENCIES OF SCALE TO POSITIVELY IMPACT THE WAY INVESTIGATORS ARE TRAINED AND COMMUNICATE BEFORE, DURING, AND AFTER CLINICAL TRIALS. TRAININGCAMPUS IS A WEB-BASED APPLICATIONS SERVICE PLATFORM THAT ALLOWS SPONSORS TO BUILD CUSTOMIZED ONLINE TRAINING AND LEARNING MODULES FOR CLINICAL RESEARCH TRAINING, TESTING, AND CERTIFICATION IN REAL TIME, REGARDLESS OF LOCATION.

There is a need for a system that is **efficient and that complies** with best practices in both the technology and medical-research arenas.

TO STREAMLINE THE PROCESS

of medical research, there is a need to create a global communications and training infrastructure that is easy for the end user - hospitals and investigative sites - and at the same time affordable for content providers and sponsors. To create a platform for that communications and training infrastructure, standardized information-technology processes are required. One way to create standardization is through Web-based, *24/7* virtual campuses that offer universal compatibility for trial training and learning for everything from preclinical to clinical to postclinical, including rater training and certification, internal training and learning, product/compound learning, name branding, and marketing.

According to Al Oviedo Pacino II, president and customer-services director of Hillicon TrainingCampus, in 1999 a group of industry leaders from the technology, medical, and clinical-research sectors formed a company called RPC Incubators. RPC elicited feedback from industry leaders from pharma, biotech, government, nonprofit organizations, hospitals and investigative sites on the best ways to create a global

infrastructure that would streamline communications and training processes in clinical research and ultimately show the actual efficiencies that could be achieved through standardization, investigative sites adaptation, and client sponsor affordability of the systems.

THE TECHNOLOGY ISSUES

According to Mr. Pacino, this research revealed that one of the biggest obstacles to streamlining the trial process was the information-technology component.

"The technology being used in our industry was not user friendly," he says. "Technology companies were building proprietary systems that were difficult to use and expensive for the client sponsors to maintain. Most technology companies lacked the necessary hands-on experience about the research industry. The inability to create systems that would yield efficiencies of scale in some instances resulted in a lack of trust between sponsors and technology providers as sponsors saw their clinical-trial budgets balloon while technology flailed to deliver promised efficiencies. IT companies were offering, and continue to sell, custom-built technology products that range from $15O,OOO to $500,000 plus.

"The initial cost of the system is compounded by the cost of maintaining that system," Mr. Pacino says. "Many small companies, such as biotech companies with only one or two products in the pipeline, can't afford the infrastructure to run a single trial. On the other end, many large pharmaceutical companies are faced with maintaining infrastructures built in the mid- to late-1990s that are stagnant and inefficient. Today's technology is cheaper, faster, and better."

Proprietary systems are not only expensive to maintain in terms of hardware and software upgrades, but they create problems for investigative sites and hospitals. Mr. Pacino maintains that just because companies spent millions of dollars building technology infrastructures doesn't mean they will work at the investigative sites, where most of the responsibility for communications and training resides.

"Many local investigative sites, such as hospitals, clinics, and private practices, resisted the use of technology, mainly because of a lack of financial resources needed to upgrade and ultimately standardize their local IT and office infrastructures," he says. "Investigators were frustrated by the many different proprietary platforms they had to adopt and to run trials. Once they adapted to one system, a new technology came along from another clinical trial- or they had to use another company's proprietary technology, thus creating a very chaotic situation at the investigative site."

According to Mr. Pacino, this is one of the main reasons that sponsors have become frustrated as well. Because it costs so much to maintain, update, and upgrade the technology, the industry has not been able to achieve the promised economies of scale. There also has been an absence of local investigative site technology as it relates to hardware, software, and bandwidth speed from which to truly derive time efficiencies.

"Most desktop and laptop technologies are slowly being standardized," Mr. Pacino says. "Up till now, software has had a more difficult standardization road; therefore investigators were confused and frustrated by requiring that they upload plug-ins onto their computers.

Case Study: Online Training in Action

AS OF FEBRUARY 2004, emergency physicians, neurologists and nurses began taking the NIH (National Institutes of Health) stroke-scale training and testing free and earning continuing education credit at the American Stroke Association's (ASA) TrainingCampus at asa.trainingcampus.net. After completing the course, participants can instantly print a course-completion certificate, which is archived on the Website, for Part I and Part II of the training.

"No other known organization offers the NIH stroke-scale training, testing, and course completion-certificate free, and physicians cannot get continuing education credits for the training anyplace else," says Thomas Brott, MD., neurologist, at the Mayo Clinic in Jacksonville, Fla., and American Stroke Association volunteer.

EMERGENCY PHYSICIANS, NEUROLOGISTS, AND NURSES GET FREE, ACCREDITED NIH STROKE-SCALE TRAINING AND TESTING ON THE AMERICAN STROKE ASSOCIATION'S TRAINING CAMPUS.

According to AI Oviedo Pacino II, president and customer services director of Hillicon TrainingCampus, two years ago the company received funding from the ASA that allowed it to continue developing a user-friendly and affordable training and communications platform.

"We also received support from CROs, pharma, and other medical entities," he says. "On February 4th of this year, the ASA, a division of the American Heart Association, unveiled its two-year initiative to train and certify raters online 24/7 on the National Institute of Health Stroke Scale."

The NIH stroke scale is a clinical-evaluation tool that medical professionals use to quantify neurologic deficit due to stroke. It is also widely used in clinical trials to assess stroke outcomes and recovery. Recently, it was used in clinical trials of tPA (tissue plasminogen activator) in ischemic stroke.

According to the ASA, medical professionals who are properly trained on the NIH stroke scale: are more timely and accurate in the diagnosis and treatment of acute stroke; improve effectiveness of patient care; increase use of acute stroke therapies; reduce stroke morbidity and mortality; improve long-term outcomes; reduce healthcare system costs; and increase patient satisfaction.

"Physicians need proper training and testing to improve their ability to accurately diagnose and treat acute stroke," Dr. Brott says.

According to Dr. Brott, because of the high demand for free and convenient training, the ASA developed an advisory group, consisting of the American Academy of Neurology (AAN) and the National Institute of Neurological Disorders and Stroke (NINDS). The group developed the NIH stroke scale training Website using a global technology platform developed by Hillicon TrainingCampus to meet the physicians' demands. As an added benefit, the training provides up to three hours of CME credits/3.6 CEU credits, which covers the needs of medical professionals who are seeking specific stroke information to maintain their accreditation.

VIEW on standardized training

to create a global infrastructure that **streamlines training processes** in clinical research.

This was a major hurdle. Efficiencies of scale do not only start from proper planning of the clinical trials, but increase or decrease algorithmically at investigative sites depending on the efficiency of technology."

Mr. Pacino maintains that today's learning and training campuses overcome the problems associated with previous technology because they are built on familiar and already used software such as Microsoft, and are compatible with any computer using Windows OS, which eliminates the need for proprietary plug-ins; furthermore, software can be upgraded free of charge.

"This reduces the costs associated with up-front software licensing fees, annual relicensing fees, maintaining, and upgrading technology, and hiring additional staff," he says.

THE INVESTIGATOR ANGLE

Investigative meeting costs also plague the clinical-trial process. Traditionally, sponsors bring investigators and their staff to a centralized location for training on the compound and good clinical practices, from Phase I through Phase IV. According co Mr. Pacino, the average cost to bring one person to a centralized location is between $1,500 and $2,200.

A virtual training campus, Mr. Pacino says, can greatly minimize and in some cases virtually eliminate these costs. E-training and e-learning management systems have standardized course maker tools, reporting tools, user community management tools, and e-commerce engines. They comply with regulatory requirements and have around-the-clock customer support. Through an electronic campus network sponsors have the ability co exchange clinical courses and content and share course modules between training campuses on demand.

"Complete investigator meetings can be put into a course format and onto their own virtual training campus so investigators, their staff clinical research associates, and study related personnel can train at their own convenience *2417* during the course of the clinical trial," Mr. Pacino says. "This increases efficiency in several respects. Training costs are reduced. Participants can complete training more quickly. Information can be tracked in a consistent and reliable manner regardless of investigator personnel turnover during the trial. Course curriculums can be specific to the clinical trial, whether a medical device or a pharmaceutical product, and can be combined with proprietary courses, such as good clinical practices or clinical scales that are owned or copyrighted by institutions or individuals."

According to Mr. Pacino, life-science industries worldwide are beginning to require continual investigator training. The best way to meet this requirement is through *2417* Web-based access to e-learning and e-training courses that can be accessed from anywhere in the world through a browser-based system.

"Regulators maintain that investigator training must be done throughout the clinical-trial process to prevent what is called clinical-trial drift," he says. "Through virtual learning modules, data can be collected in real time allowing sponsors to prove to the FDA that the sites were well trained, and continuously trained."

TRAINING ADVANTAGES

According to Mr. Pacino, because a trial-training campus can work from the Same infrastructure, sponsors do not have to reinvent the process every time a clinical trial is initiated.

"Maintaining a *2417* trial-training and learning campus before, during, and after clinical trials can complement, and in some cases, limit the need to have seasonal investigator meetings," he says. "Campuses allow the sponsor to give the FDA concrete proof that site personnel acquired proper knowledge about the studied products, by providing continued training and learning assessment and by measuring and collecting an investigator's knowledge base in real-time."

Another advantage of a virtual campus is rater training and certification. Investigative site personnel can train and certify raters online on specialized clinical scales.

"Clinical-rating scales are standard questions and answers, which arc commonly used by physicians and their staffs to assess patients' level of injury/sickness, and are a common tool used to recruit patients in a standardized manner," Mr. Pacino says. "Raters require specialized training and certification from experts in their field. This is especially important in the therapeutic areas of stroke and CNS, where rating scales are required. Sponsors have to initiate proof to the FDA that physicians and their staffs have been trained to recruit patients through these standardized rating scales.

Nowadays, our global industry requires nor only that training and certification be documented, prior to recruiting patients, but in most cases and because of trial-drift, that subsequent recalibrations be performed every three to six months. This is rapidly becoming an expensive and inefficient preposition in clinical trials.

"For example, take a company that is initiating a two-year study and needs to train 35 investigative sites every three months on the same scale," Mr. Pacino says. "An online training campus can eliminate the expense of bringing 150 investigators to a centralized location, while at the same time, allowing reports and metrics to be generated in real time from all involved investigative sites."

A training campus can also help managers improve internal training and assess the knowledge of its employees on specific topics by allowing them to customize training and collect and analyze the staffs knowledge From the desktop.

Product and compound learning can be improved by training personnel and investigators about a company's products before, during, and after the clinical trials thus increasing the success rate for future marketing strategies.

Name branding and recognition can be improved by creating a constant reminder to physicians and their staff through a sponsor-branded campus.

Mr. Pacino adds that online campuses help marketing teams set up and maintain long-term strategies, as well as introduce new product offerings. Distributors, physicians, and their staff can enter a campus to learn about new products at their own convenience.

"There are many training technology software companies out there, but until now, there has been no standard training technology for clinical trials," Mr. Pacino says. "There was a need to create a system that would nor only be efficient, but that would comply with best practices in both the technology and medical research arenas. Through a Web-based applications service platform that allows sponsors to build customized online training and learning modules for clinical research training, testing, and certification in real time, collect and measure trial knowledgebase in real time, regardless of location." t

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